8 August 2011

Senate Finance and Administration References Committee

Medicines Australia Responses to Questions on Notice

Questions for Medicines Australia

1. **Do you agree with the Managing Director of Pfizer that there has been an actual breach of the text of the MOU, or not? I've seen comments from Medicines Australia referring to the 'spirit' and the 'intent' of the MOU, which suggests a different view than that of Mr Latham.**

   Medicines Australia represents the industry view of some 50 member companies. Individual member companies of course retain the right to express a company specific position on matters affecting them.

   Given the level of uncertainty that the Government has injected into the PBS listing process this year it comes at no surprise that members of the industry express nuanced views about whether the Government has breached the explicit terms of the MoU or 'merely' the spirit.

   As Dr Brendan Shaw stated in his cover letter to the Senate Finance and Administration References Committee Inquiry, "Medicines Australia strongly believes that the Australian Government has breached the intent, if not strictly the letter, of this agreement". Medicines Australia has not changed its position.

2. **In the most recent Budget, Medicines Australia publicly noted there were no price-related savings measures, as per the MOU?**

   Medicines Australia welcomed the fact that there were no PBS price-related savings measures in this years' Federal Budget. Medicines Australia has a track record of working collaboratively with governments of all persuasions over a number of years, applauding good policy and criticising bad policy decisions.

   Medicines Australia issued a media release on 13 May 2011 to say that no new announcements were in the Budget and stated that, "However, while we appreciate the Government respecting the provisions of the MoU, we strongly disagree with the Cabinet's decision to block the listing of new medicines on the PBS, which contradicts the intent of the MoU."

   Full text of the May 13 press release follows:

   No pricing cuts to PBS in Budget

   The fact that the 2011 Budget had no PBS price-related savings measures, as per the Memorandum of Understanding between Medicines Australia and the Government, is welcome.

   The MoU, which was signed in May 2010, was the result of tough negotiations between the Government and industry, and delivered savings to taxpayers, savings to consumers and process improvements to the PBS.

Medicines Australia chief executive Dr Brendan Shaw said: "In respect of delivering savings to the PBS, the MoU is working well and this week's Budget is testament to that. The MoU provides a good framework for managing the PBS agreed between the Government and industry.

"However, while we appreciate the Government respecting the provisions of the MoU, we strongly disagree with the Cabinet's decision to block the listing of new medicines on the PBS, which contradicts the intent of the MoU."

In February, Federal Cabinet deferred indefinitely the PBS listing of seven new medicines and a vaccine which had been recommended for listing by the Government's own committee of clinical and health economics experts.

Dr Shaw welcomed the eventual decision to subsidise in the Budget the pneumococcal vaccine catch-up for children that had been delayed by Cabinet since February.

"This is a good decision, but we hope the Government will list all other deferred medicines as soon as possible," Dr Shaw said.

Medicines Australia also applauds the support of the Pharmaceutical Benefits Scheme by the Leader of the Opposition in his Budget Reply speech to the House of Representatives last night.

Tony Abbot said in his speech: "We won't turn the Pharmaceutical Benefits Scheme from a demand-driven to a budget-limited scheme by not listing drugs that have passed an expert cost-effectiveness test."

Mr Abbott's comments reflect the importance of maintaining the integrity of the PBS processes.

Medicines Australia also welcomes the Greens' support for the timely PBS listing of medicines that have been recommended by the Pharmaceutical Benefits Advisory Committee.

Greens health spokesperson Senator Rachel Siewert noted in a recent media release about the Cabinet's decision to defer PBS listings:

"This will have significant implications for Australians trying to access these medicines."

–ENDS–

3. Can you run us through some of the other Government components of the MOU -- in particular, parallel processing and managed entry. I understand some of these reforms are already starting to come to fruition, with listings come through for the July PBAC meeting?

The Memorandum of Understanding (MoU) was announced by the Australian Government in the Federal Budget 2010-11. It is designed to fulfil the objectives of Australia's National Medicines Policy particularly the first objective, 'timely access to the medicines Australians need, at a cost individuals and the community can afford'. It was in that context that a range of system improvements to the PBS were negotiated for insertion into the MoU, to improve patients' access to medicines. These include but are not limited to:

- Date of lodgement of a TGA registration dossier. Sponsors will be permitted to submit the TGA delegate's overview up to one week prior to the PBAC meeting (at the same time the pre-PBAC responses are provided to the PBAC Secretariat).
    - The PBAC timelines are quicker than those of the TGA: four months from lodgement to PBAC consideration, compared to a minimum of seven months

from lodgement to an initial overview by the TGA delegate, a further month for consideration by the Advisory Committee on Prescription Medicines (ACPM) and a further month for the final registration decision (giving a total of nine months).

- This will be the fastest timeline under the revised TGA arrangements which will come fully into effect in November 2011. This means that if applications are lodged simultaneously to TGA and PBAC, which is an option proposed under the MOU, PBAC consideration would precede any consideration by TGA."

- The managed entry of a medicine on to the PBS. The PBAC website updated as at 18 February 2011 provides information on the managed entry scheme (http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions which notes that:

  "In summary, a submission that would normally be rejected by the PBAC because of uncertainty around the true extent or value of the clinical effect could be recommended under a managed entry scheme provided the managed entry parameters are met. This would mean:

  - earlier access to the drugs by patients;
  - earlier access to a subsidised market for the sponsor (at an initial price considered by the PBAC to be acceptable given the available evidence at the time);
  - clear articulation by the PBAC of the critical areas of uncertainty along with comment on whether based on the information provided the trial design is likely to resolve such uncertainty;
  - agreement by the PBAC to review a resubmission once the additional data becomes available and to reconsider the price in light of the new evidence."

In her second reading of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010, which would give effect to the savings measures in the MoU, Minister Roxon noted:

> "The Bill also embodies an historic level of co-operation and collaboration between the Government and the pharmaceutical industry, represented by Medicines Australia. Through jointly negotiating these reforms, the Government and the industry will help ensure the sustainability of the PBS for years to come...The viability of the medicines industry in Australia also needs to be maintained....The MoU sets out...the policy innovations that will be introduced to improve the pathway for subsidy of medicines under the PBS...Further process and policy changes for the listing of PBS medicines under the MoU will reduce red tape and further foster the availability of new medicines in Australia." (29 September 2010)

4. What's Medicines Australia's view on the government's determination to pass and implement the R&D tax credit?

Medicines Australia supports good policy and opposes bad policy. Medicine Australia has a strong and consistent record of supporting the implementation of the R&D Tax Credit system, because it is good policy.

Indeed, Medicines Australia has invested considerable resources over recent years supporting the Government's initiative on the grounds that it will replace the outdated, unpredictable and overly complicated R&D Tax Concession system, which has failed to help Australian companies attract a larger share of the global bio-pharmaceutical industry's R&D investment budget (worth approximately $70 billion annually). The new system will make access to tax benefits more predictable, and it will help reduce the cost of conducting eligible R&D in Australia by up to 10%.

Medicines Australia is proud of the fact that it has been one of the business groups to strongly support the Government's new R&D tax credit. The industry shares the Government's policy objective to encourage more R&D, investment, exports and high-skilled jobs in Australia. Medicines Australia has for several years worked hard in partnership with the Government to help explain to the community the benefits to Australia of the policy change.

Medicines Australia's most recent media release from 15 June 2011 supporting the changes is reproduced below:

R&D tax credit to boost Aussie medical research

Medicines Australia welcomes the Government's announcement today that it has the support of the Australian Greens to pass the R&D tax credit Bill in the Senate.

The new tax credit will reduce the cost of eligible R&D by 10 per cent and make Australia more internationally competitive as a destination for medical research investment, Medicines Australia's acting chief executive Andrew Bruce said.

"R&D sustains Australia's $18 billion medicines industry and provides thousands of jobs," Mr Bruce said.

"This legislation will provide companies with an additional incentive to boost their R&D investment in Australia.

"Competition for R&D investment dollars from Asia and Europe is fierce, and we have been falling behind. With the right policy settings we can reverse this decline.

"We have the right people in Australia to run these medicine development programs and we have good infrastructure. We just need to make it attractive for companies to invest in Australia.

"This legislation is a big step in the right direction to ensure Australia remains competitive in the face of strong overseas competition.

"It will help keep more of our top research scientists engaged in Australian R&D and attract greater investment to our universities and other research institutions.

"I congratulate the Government, along with the Australian Greens for supporting this important legislation.

"The Minister for Innovation Senator Kim Carr has long been a strong supporter of Australian research in general and the medicines industry in particular.

"His advocacy of the new tax credit is a great example of that support."

The Australian medicines industry attracted more than $1 billion in R&D investment in 2010. In any given year around18,000 Australians take part in clinical trials.

5. **How has the Government been progressing with the Clinical Trials Action Group recommendations? Do you agree with the steps Government is taking to streamline clinical trial approval processes?**

   Medicines Australia has strongly supported the implementation of the Clinical Trials Action Group (CTAG) recommendations. Medicines Australia notes there has been some slippage in the Government's original timelines but remains closely involved and committed to the implementation. Medicines Australia is a member of the Coordination Group that the Ministers for Innovation and Health have established. The Chair of the Pharmaceuticals Industry Council (PIC) R&D Taskforce is also a member of this Group.

   Of course, industry would like the CTAG recommendations to be implemented as soon as possible, and in accordance with the timelines recommended by the Ministers. This will require strong, committed leadership from the Ministers, their Departments and the NHMRC, as well as agreement from the jurisdictions (in particular) to implement the policy changes.

   Medicines Australia and its member companies have been keen supporters of the Government's policy objective to encourage more R&D, investment, exports and high-skilled jobs in Australia. Again, it has been Medicines Australia that has been a key player in supporting the Government's policy agenda by helping to explain to stakeholders and the community the benefits of the Government's policy change.

6. **Parallel processing, managed entry, R&D tax credits, streamlining clinical trials -- the Government seems to have built up a fair track record of assistance to industry over the past couple of years. Of course industry has done its part as well, but do you consider that all of these reforms are outweighed by the temporary deferral of 6 drugs, at the same time 124 have been listed at a cost over $600M this year alone?**

   No. Medicines Australia does not view improving the policy environment as seeking assistance from Government. Rather the improvements to the system are about providing access to medicines for Australians, in a timely and cost effective manner as a benefit to member companies, Australian patients and the community as a whole. The purpose of the MoU was to create a stable policy environment where industry could undertake its business without constant reference to government. It is not some form of 'industry assistance'.

   While all of the policy issues raised in this question contribute to the policy environment in which industry operates, it is not a question of whether one policy outweighs another. Rather, it is a case that some policies are evidenced-based, strategic initiatives and others are not well thought out and will have a negative impact on patients and companies alike.

Medicines Australia believes that the figure of '124 medicines listed at a cost of over $600M' articulated by the Government is, in fact, incorrect, or is likely to be misinterpreted. Independent analysis by Victoria University indicates that only 20 new medicines have been listed this financial year. This is 100 less than the Government claims. It appears that the Government may have attributed the extension of uses of medicines or the adding of new brands of existing off-patent F2 medicines already on the PBS as 'new' listings and in doing so the figures in this claim appear incorrectly inflated. We note that the listings in the F2 market are a key component for delivering market driven savings to the Government, a process Medicines Australia has worked on with the Government to make more efficient.

In its original submission to the Senate Inquiry, Medicines Australia presented evidence demonstrating that PBS growth is at a sustainable level, well below long term averages and that it remains stable as a percentage of GDP. As the information and table below show, the Government is realising the benefits of reforms to the PBS, downwards pressures on PBS growth appear to have been overlooked when arriving at the $600m figure referred to in the question.

Finally, the unfortunate decision by the Government to defer the listing of a number of new medicines and vaccines, without consultation with the industry, sends mixed messages to companies that may be considering future R&D, clinical trials and investment in Australia. On the one hand, the Government is making good policy changes like the R&D tax credit, clinical trials regulatory reform and the Memorandum of Understanding to provide an attractive, stable policy environment which does play a role in attracting the interest of companies to undertake such activities. On the other hand, the deferrals decision by Cabinet sends the opposite signal to companies, namely that a company cannot be at all confident that its future investment in R&D is going to be recognised and respected by the Government.

It suggests that, in this instance, the Government has failed to adopt a 'whole of government' approach to policy, namely introducing new incentives for investment while at the same time dissuading that investment. Just in the last week, Medicines Australia again received feedback from a global pharmaceutical company that how a medicine proceeds through the PBS listing process *does* directly impact on the company's decision whether to locate clinical trials in Australia.

Such confused, mixed messages only make it more confusing for companies, who, with competing locations for such investment, may pass Australia by. The deferrals decision certainly does not help the Government's other policy objectives of encouraging more R&D and investment in Australia.

Price disclosure price cuts to date[1]

At April 2011, there were some 28 medicines that had listing dates for the first mandatory brand which lay between the first such date (1 August 2007) and 1 April 2009 (DOHA 2010). Medicines listed after the latter date could not have yet had a price disclosure price cut. Of these 28, 15 (54%) had actually experienced these cuts, meaning 13 had not. The average cost to the Government in 2009-10 of the ones that had cuts was $16.1 million and 8 of them had PBS costs over $10 million. Of those that did not have price cuts, the average cost was $8.6 million and only 4 cost more than $10 million.

[1] Independent analysis by Centre For Strategic Economic Studies into price disclosure

The table below lists those medicines that have had a price cut. It shows the percentage change in the Commonwealth price to the pharmacist for the manufacturer's pack (CPPMP) for those medicines that have had price disclosure price cuts. These are slightly different from the price cuts reported at the ex-manufacturer level. In addition it gives the cost to the Government of that medicine in 2009-10.

Name	Form	Government cost 2009-10 $m	First reduction date	First round change %	Second round change %	Cumulative change %
Alendronic acid	Oral	29.7	201104	21.4		21.4
Carvedilol	Oral	36.9	201004	25.8	11.9	34.6
Cefalotin	Injection	0.8	201008	41.1		41.1
Cisplatin	Injection	0.8	201104	37.8		37.8
Doxorubicin	Injection/Intravesical	13.8	200912	62.8	34.6	75.7
Fluconazole	Injection	7.8	201004	54.3	38.5	71.9
Fluconazole	Oral	0.4	201104	26.0		26.0
Gemcitabine	Injection	17.6	201104	35.7		35.7
Irinotecan	Injection	17.9	201104	60.6		60.6
Meloxicam	Oral	36.8	201008	18.0		18.0
Mitozantrone	Injection	0.6	200912	33.1	13.3	42.0
Ondansetron	Injection	1.2	200912	13.6	17.6	28.8
Paclitaxel	Injection	38.8	201104	51.6		51.6
Risperidone	Oral	34.2	201104	15.7		15.7
Vancomycin	Injection	3.7	201004	71.2	12.5	74.8
Average first round				37.9		
Two round average				43.5	21.4	54.6